

REMARKS

Upon entry of the present amendments, claims 163-168, 170-171, 173-180, 182-188, 190-198, and 200-206 constitute the pending claims in the present application. Claims 169, 172, 181, 189, and 199 were previously cancelled. No amendments are made herein. The listing of the claims is included for the convenience of the Office.

Telephonic Interview

Applicants appreciate the time and attention of Examiner Lacyk during the productive telephonic interview of June 3, 2008. During the interview, the outstanding rejections over U.S. Patent No. 5,336,231 to Adair ("Adair") in view of Norris et al. "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach" ("Norris") and over U.S. Patent No. 4,935,027 to Yoon ("Yoon") in view of Norris were discussed. In particular, Applicants' agent indicated that considering the non-analogous teachings of Adair and Yoon, one of ordinary skill in the art would not have been motivated to combine these references with Norris. Applicants' agent also indicated that one of ordinary skill in the art would not have had a reasonable expectation of success in combining Adair or Yoon with Norris. Examiner Lacyk agreed that one of ordinary skill in the art would not have been motivated to combine Adair or Yoon with Norris and acknowledged that the pending claims patentably distinguish over these references. However, the Examiner noted that a further search and examination of the claims might be required.

Below Applicants present in more detail the discussion from the above telephonic interview request reconsideration in view of these remarks. Issues raised by the Office are addressed below in the order they appear and using the enumeration from the outstanding Office Action.

1-3. Claim Rejections – 35 U.S.C. 103(a) – Claims 175-180, 185-188

Claims 175-180 and 185-188 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Adair in view of Norris. Applicants respectfully traverse the rejection.

In Item 3 of the outstanding Office Action, the Office concludes that Adair teaches the claimed system except for "the sling being specifically in a flat shape" and then relies on Norris for this feature. The Office asserts that modification of the wire-like suture of Adair with the flat sling

of Norris would have been obvious “since the flat shaped sling would provide a little more surface area and allow for added support to treat incontinence.”

Applicants respectfully disagree and note that Adair does not provide systems and/or methods for treating urinary incontinence. Rather as indicated in the graphic depiction of FIGS. 10-17 of Adair, this reference teaches the technique of ligating body tissue, which is wholly opposite of the technology claimed by Applicants. As seen in FIG. 17, the portion 52 of the fallopian tube 50 is pinched from the remainder using the Adair method and device. If such a method were applied to urinary incontinence, it would result in destruction of the patient’s urethra, complete loss of continence, and no useful results at all. One of ordinary skill in the art would not have been motivated to combine the teachings of Adair with Norris for treating urinary incontinence since Adair teaches only methods that would result in incontinence. In short, Adair teaches away from such a combination.

Applicants further submit that one of ordinary skill in the art would not have had a reasonable expectation of success in combining the alleged flat-shaped sling of Norris with the device of Adair as suggested by the Office. Specifically, Adair provides a device that facilitates tying sutures into knots in order to ligate tissue. First, Adair ties sutures with circular cross-sections into knots (see FIG. 2). The use of a suture with a flat cross-section, as suggested by the Office, would result in a weak and fragile knot since the edges possessed by a flat shape would cut into adjacent portions of the suture when the knot is tightened, thereby defeating the utility of the Adair device and methods. Second, the Adair device includes multiple passageways (e.g., passageway 16), which are circular in diameter for ease of passage of the circular diameter suture. Flat sutures would not flow as easily and may clog the passageways of the Adair system, again resulting in an inferior device. Hence, the ordinary skilled artisan would have recognized the incompatibility of the Adair and Norris references as advanced by the Office and would not have had a reasonable expectation of success in their combination.

Pursuant to MPEP 2142:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the

reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Since combination of the teachings of Adair and Norris as envisaged by the Office would have been without motivation or reasonable expectation of success, these references cannot sustain an obviousness rejection over claims 175 or 185 or those dependent thereon, and Applicants request reconsideration and withdrawal of the obviousness rejection over Adair in view of Norris.

Claim Rejections – 35 U.S.C. 103(a) – Claims 193-198

Claims 193-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Norris. Applicants respectfully traverse the rejection.

The defects present in Adair are also present in Yoon. Specifically, in Item 5 of the outstanding Office Action, the Office acknowledges Yoon does not teach or suggest a flat-shaped sling and relies on Norris for this feature. However, Yoon, like Adair, is a device for tying sutures into knots. Yoon does not teach or suggest any use for treating urinary incontinence, and so one of ordinary skill in the art would not have had any motivation to combine the teachings of Norris with those of Adair.

The combination of Yoon and Norris also would not have had a reasonable expectation of being successful. As noted above for Adair, knots tied from sutures with flat shapes would be less operable than those with circular cross-sections since the edges resulting from the flat shape would cut into neighboring portions of the suture that comprise the knot and also into the adjacent tissues of the patient. Also, the Yoon device, like that of Adair, includes numerous channels and, additionally, pulleys, all of which operate with a suture with a circular cross-section (see, for example, FIGS. 12A and 16-18, which depict the circular cross-section of suture 30). An alleged suture with a flat cross-section as taught in Norris would clog and foul the Yoon device, especially once the suture became twisted. Yet, the Yoon device is predicated on smooth passage and continuous feed of the suture through the numerous channels and pulleys (see Yoon abstract), and so the use of a flat suture would impede Yoon's purpose.

Moreover, the combination of Yoon and Norris does not teach or suggest all the features of claim 193, for example “a sling assembly comprising ... an end for associating with the channel of the shaft.” Applicants respectfully submit that the Office has not established how Yoon and Norris teach or suggest these features. Accordingly, Applicants submit that the Office has not satisfied its burden in establishing a *prima facie* case of obviousness.

Since the combination of Yoon and Norris advocated by the Office fails to satisfy the requirements for establishing a *prima facie* case of obviousness, these references cannot render claim 193 or those dependent thereon obvious, *In re Vaeck, supra*, and Applicants request reconsideration and withdrawal of the obviousness rejection over Yoon in view of Norris.

Claim Rejections – 35 U.S.C. 103(a) – Claims 182-184, 190-192 and 204-205

Claims 182-184, 190-192 and 204-205 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair in view of Norris and further in view of U.S. Patent No. 3,580,256 to Wilkinson et al. (“Wilkinson”). Applicants respectfully traverse the rejection.

As noted above, one of skill in the art would not have had any motivation or a reasonable expectation of success in combining the teachings of Adair with those of Norris, and Wilkinson fails to cure this defect. As such, a *prima facie* case of obviousness has not been established, and Applicants request reconsideration and withdrawal of the rejection.

Claim Rejections – 35 U.S.C. 103(a) – Claims 163-168, 170-171, 173-174 and 203

Claims 163-168, 170-171, 173-174 and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Norris et al and further in view of Wilkinson. Applicants respectfully traverse the rejection.

As noted above, one of skill in the art would not have had any motivation or a reasonable expectation of success in combining the teachings of Yoon with those of Norris, and the combination would also fail to teach all of the features of the present claims. Since Wilkinson fails to cure these defects, a *prima facie* case of obviousness has not been established.

Additionally, the Office acknowledges that Yoon does not teach or suggest the pouch feature of claim 163 but asserts that Wilkinson provides this element and refers to FIGS. 1 and 7 (see Items 14-15 of the outstanding Office Action). These figures depict the casing 13, which Wilkinson teaches to be a “thin film coating ... formed by dipping or spraying” (see column, lines 60-61 of Wilkinson). Applicants submit that a coating is structurally distinct from a pouch and, accordingly, that the combination of Yoon, Norris, and Wilkinson also fails to teach or suggest all of the features in the present claims. Furthermore, the Office has not demonstrated a proper motivation for modifying the Yoon and Norris devices with the alleged pouch of Wilkinson. Although the Office submits that “pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects,” no references are provided for this unsupported statement.

Accordingly, for these several reasons, Applicants request reconsideration and withdrawal of the rejection of claim 163 and those dependent thereon.

Claim Rejections – 35 U.S.C. 103(a) – Claims 200-202 and 206

Claims 200-202 and 206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Norris as applied to claim 193 in view of Wilkinson. Applicants respectfully traverse the rejection. For the reasons above, Applicants assert that a *prima facie* case of obviousness over Yoon in view of Norris in view of Wilkinson has not been established, and Applicants request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the above arguments and amendments, Applicants believe the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.


Reply dated July 1, 2008
In Reply to Final Office Action of February 12, 2008

Application No.: 10/774,826
Docket No.: MIY-P03-006

Should an extension of time beyond that mentioned above be required, Applicants hereby petition for same and request that the additional extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945, under Order No. MIY-P03-006 from which the undersigned is authorized to draw.

Dated: July 1, 2008

Respectfully submitted,

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